

**APPENDIX D**  
**Written Description Support in the Priority Applications**

<b>Applicant's Claims</b>	<b>Application Support</b>
1. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:	“The insertion of vertebral fixation elements can also be accomplished through the device 10.” U.S. Patent No. 5,792,044 (“the '044 patent) at col. 15, lines 3-4; U.S. Patent No. 6,007,487 (“the '487 patent) at col. 15, lines 10-11; U.S. Patent No. 6,520,907 (“the '907 patent) at col. 15, lines 3-4; U.S. Published Patent Application No. 2003/0139648 (“the '648 published application) at ¶ 0077.
inserting a cannula into the patient;	“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” '044 patent at col. 15, lines 7-9; '487 patent at col. 15, lines 14-17; '907 patent at col. 15, lines 7-10; '648 published application at ¶ 0077.
inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;	“The insertion of vertebral fixation elements can also be accomplished through the device 10.” '044 patent at col. 15, lines 3-4; '487 patent at col. 15, lines 10-11; '907 patent at col. 15, lines 3-4; '648 published application at ¶ 0077.  “In one specific embodiment, the fixation element can be a bone screw. . . . Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision.” '044 patent at col. 15, lines 12-27; '487 patent at col. 15, lines 20-36; '907 patent at col. 15, lines 12-27; '648 published application at ¶ 0077-0078.
inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and	“The insertion of vertebral fixation elements can also be accomplished through the device 10.” '044 patent at col. 15, lines 3-4; '487 patent at col. 15, lines 10-11; '907 patent at col. 15, lines 3-4; '648 published application at ¶ 0077.  “In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single

	<p>working channel cannula.” ’044 patent at col. 4, lines 12-15; ’487 patent at col. 4, lines 16-19; ’907 patent at col. 4, lines 11-14; ’648 published application at ¶ 0018.</p> <p>“The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’487 patent at col. 15, lines 39-42; ’907 patent at col. 15, lines 31-34; ’648 published application at ¶ 0078.</p>
<p>inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’487 patent at col. 15, lines 10-11; ’907 patent at col. 15, lines 3-4; ’648 published application at ¶ 0077.</p> <p>“The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’487 patent at col. 15, lines 39-42; ’907 patent at col. 15, lines 31-34; ’648 published application at ¶ 0078.</p>
<p>2. The method of claim 1, further comprising the step of positioning an endoscope in the cannula to provide a view of the activity at the surgical site.</p>	<p>“An elongated viewing element 50 is mountable inside cannula 20 adjacent the working channel 25.” ’044 patent at col. 5, lines 51-52; ’487 patent at col. 5, lines 55-56; ’907 patent at col. 5, lines 51-52; ’648 published application at ¶ 0040.</p> <p>“The viewing element 50 can be of a variety of types, including a rigid endoscope or a flexible and steerable scope.” ’044 patent at col. 11, lines 39-41; ’487 patent at col. 11, lines 45-47; ’907 patent at col. 11, lines 39-41; ’648 published application at ¶ 0063.</p>
<p>3. The method of claim 1, further comprising the steps of:</p> <p>removing a disk from between the first and second vertebrae;</p>	<p>“Again under direct vision, the disc space can be prepared for implantation of fusion materials or a fusion device. Typically, this preparation includes preparing an opening in the disc annulus, and excising all or part of the</p>

	disc nucleus through this opening.” ’044 patent at col. 15, lines 51-55; ’487 patent at col. 15, lines 59-63; ’907 patent at col. 15, lines 51-55; ’648 published application at ¶ 0079.
cleaning the area of the surgical site;	“In addition, during a discectomy, aspiration of the excised tissue is preferred, and irrigation will frequently assist in rapid removal of this tissue.” ’044 patent at col. 13, lines 21-24; ’487 patent at col. 13, lines 28-31; ’907 patent at col. 13, lines 21-24; ’648 published application at ¶ 0071.
positioning a fusion device between the first and second vertebrae by moving the fusion device through the cannula; and	“The devices can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.” ’044 patent at col. 15, lines 35-37. “The device 10 can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.” ’487 patent at col. 15, lines 43-45; ’907 patent at col. 15, lines 35-37; ’648 published application at ¶ 0079.  “A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device and into the prepared bore at the subject disc space.” ’044 patent at col. 15, lines 57-61; ’487 patent at col. 15, line 65-col. 16, line 2; ’907 patent at col. 15, lines 57-61; ’648 published application at ¶ 0080.
positioning bone graft tissue in and around the surgical site by moving bone graft tissue through the cannula.	“In some instances, graft material is simply placed within the prepared bore. This graft material can also be passed through the working channel cannula 20 into the disc space location. In other procedures, graft material or bone chips are positioned across posterior aspects of the spine. Again, this procedure can be conducted through the working channel cannula particularly given the capability of the cannula to be moved to different angles from a single incision site in the skin.” ’044 patent at col. 16, lines 1-9; ’487 patent at col. 16, lines 9-16; ’907 patent at col. 16, lines 1-9; ’648 published application at ¶ 0081.
4. The method of claim 1, further comprising	“A tissue retractor and discectomy instruments

<p>the step of cutting away tissue at the surgical site using a cutting instrument.</p>	<p>can be simultaneously extended through the working channel. In that illustrated embodiment, the discectomy instruments could include a trephine for boring a hole through the disc annulus and a powered tissue cutter for excising the herniated disc nucleus.” ’044 patent at col. 14, lines 41-46; ’487 patent at col. 14, lines 48-54; ’907 patent at col. 14, lines 42-46; ’648 published application at ¶ 0076.</p>
<p>5. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’487 patent at col. 15, lines 10-11; ’907 patent at col. 15, lines 3-4; ’648 published application at ¶ 0077.</p>
<p>inserting a cannula into the patient;</p>	<p>“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” ’044 patent at col. 15, lines 7-9; ’487 patent at col. 15, lines 14-17; ’907 patent at col. 15, lines 7-10; ’648 published application at ¶ 0077.</p>
<p>moving a fusion device through the cannula and inserting the fusion device between first and second vertebrae of the patient;</p>	<p>“The devices can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.” ’044 patent at col. 15, lines 35-37. “The device 10 can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.” ’487 patent at col. 15, lines 43-45; ’907 patent at col. 15, lines 35-37; ’648 published application at ¶ 0079.</p> <p>“A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device and into the prepared bore at the subject disc space.” ’044 patent at col. 15, lines 57-61; ’487 patent at col. 15, line 65–col. 16, line 2; ’907 patent at col. 15, lines 57-61; ’648 published application at ¶ 0080.</p>
<p>inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’487</p>

	<p>patent at col. 15, lines 10-11; '907 patent at col. 15, lines 3-4; '648 published application at ¶ 0077.</p> <p>"In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula." '044 patent at col. 4, lines 12-15; '487 patent at col. 4, lines 16-19; '907 patent at col. 4, lines 11-14; '648 published application at ¶ 0018.</p> <p>"In one specific embodiment, the fixation element can be a bone screw. . . . Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision." '044 patent at col. 15, lines 12-27; '487 patent at col. 15, lines 20-36; '907 patent at col. 15, lines 12-27; '648 published application at ¶ 0077-0078.</p>
<p>inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and</p>	<p>"The insertion of vertebral fixation elements can also be accomplished through the device 10." '044 patent at col. 15, lines 3-4; '487 patent at col. 15, lines 10-11; '907 patent at col. 15, lines 3-4; '648 published application at ¶ 0077.</p> <p>"The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw." '044 patent at col. 15, lines 31-34; '487 patent at col. 15, lines 39-42; '907 patent at col. 15, lines 31-34; '648 published application at ¶ 0078.</p>
<p>inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.</p>	<p>"The insertion of vertebral fixation elements can also be accomplished through the device 10." '044 patent at col. 15, lines 3-4; '487 patent at col. 15, lines 10-11; '907 patent at col. 15, lines 3-4; '648 published application at ¶ 0077.</p> <p>"The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to</p>

	<p>receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’487 patent at col. 15, lines 39-42; ’907 patent at col. 15, lines 31-34; ’648 published application at ¶ 0078.</p>
<p>6. The method of claim 7, further comprising the step of inserting a tissue retractor into the cannula and shielding tissue at the surgical site.</p>	<p>“Once the spinal nerve root is exposed, a retractor, such as the retractors shown in FIGS. 4-8, can be used to gently move and hold the nerve root outside the working space. In one important aspect of the two retractors 70, 100, the portion of the retractor passing through the working channel 25 generally conforms to the inner surface of the cannula 20 so that the working channel 25 is not disrupted by the retractor tool.” ’044 patent at col. 14, lines 8-14; ’487 patent at col. 14, lines 15-21; ’907 patent at col. 14, lines 8-14; ’648 published application at ¶ 0074.</p>
<p>7. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; U.S. Patent No. 5,902,231 (“the ’231 patent”) at col. 22, lines 22-23; U.S. Patent No. 6,217,509 (“the ’509 patent”) at col. 22, lines 28-29; “The insertion of vertebral fixation elements can also be accomplished through the devices.” U.S. Patent No. 6,679,833 (“the ’833 patent”) at col. 21, lines 56-57.</p>
<p>inserting a cannula into the patient;</p>	<p>“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” ’044 patent at col. 15, lines 7-9; ’231 patent at col. 22, lines 26-29; ’509 patent at col. 22, lines 32-35; ’833 patent at col. 21, lines 60-63.</p>
<p>expanding the cannula;</p>	<p>“In accordance with a further variation of the present invention, the cannula 20 can be replaced by a similar device that is capable of maintaining a large working channel 25. For example, the cannula 20 can be replaced by an expanding cannula or dilator apparatus. In one specific embodiment, the apparatus can be a spiral wound tube that is unwound or expanded to provide the working channel dimension.” ’231 patent at col. 9, lines 40-46; ’509 patent at col. 9, lines 46-53; ’833 patent at col. 9, lines 46-53.</p>

<p>inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’231 patent at col. 22, lines 22-23; ’509 patent at col. 22, lines 28-29;  “The insertion of vertebral fixation elements can also be accomplished through the devices.” ’833 patent at col. 21, lines 56-57.</p> <p>“In one specific embodiment, the fixation element can be a bone screw. . . . Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision.” ’044 patent at col. 15, lines 12-27; ’231 patent at col. 22, lines 32-48; ’509 patent at col. 22, lines 38-54; ’833 patent at col. 21, line 66, to col. 22, line 15.</p>
<p>inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra;</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’231 patent at col. 22, lines 22-23; ’509 patent at col. 22, lines 28-29;  “The insertion of vertebral fixation elements can also be accomplished through the devices.” ’833 patent at col. 21, lines 56-57.</p> <p>“Therefore, according to this invention, an entire percutaneous surgical procedure can be performed through the working channel 25 of the device 10 under direct visualization using the viewing element 50 disposed within the optics bore 60.” ’044 patent at col. 7, lines 61-65; ’231 patent at col. 9, lines 14-18; ’509 patent at col. 9, lines 20-24; ’833 patent at col. 9, lines 17-21.</p> <p>“The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’231 patent at col. 22, lines 51-54; ’509 patent at col. 22, lines 57-60; ’833 patent at col. 22, lines 18-21.</p>
<p>inserting a third fixation element through the cannula and securing the third fixation element</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device</p>

to the first and second fixation elements.	<p>10.” ’044 patent at col. 15, lines 3-4; ’231 patent at col. 22, lines 22-23; ’509 patent at col. 22, lines 28-29; “The insertion of vertebral fixation elements can also be accomplished through the devices.” ’833 patent at col. 21, lines 56-57.</p> <p>“The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’231 patent at col. 22, lines 51-54; ’509 patent at col. 22, lines 57-60; ’833 patent at col. 22, lines 18-21.</p>
8. The method of claim 7, further comprising the step of shifting the cannula in the body to position the cannula at a desired location in the body.	<p>“As necessary, the cannula 20 can be angled to allow a greater region of bone removal, which may be necessary for access to other portions of the spinal anatomy.” ’044 patent at col. 13, lines 54-56; ’231 patent at col. 15, lines 43-45; ’509 patent at col. 15, lines 50-52; ’833 patent at col. 15, lines 12-14.</p> <p>“Again, this procedure can be conducted through the working channel cannula particularly given the capability of the cannula to be moved to different angles from a single incision site in the skin.” ’044 patent at col. 16, lines 5-9; ’231 patent at col. 23, lines 25-29; ’509 patent at col. 23, lines 31-35; ’833 patent at col. 22, lines 60-64.</p>
9. A method of fixing vertebrae of a patient together at a surgical site comprising the steps of:	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’487 patent at col. 15, lines 10-11; “the ’907 patent at col. 15, lines 3-4; ’648 published application at ¶ 0077.</p>
inserting a cannula into the patient;	<p>“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” ’044 patent at col. 15, lines 7-9; ’487 patent at col. 15, lines 14-17; ’907 patent at col. 15, lines 7-10; ’648 published application at ¶ 0077.</p>
moving a plurality of fixation elements through	<p>“The insertion of vertebral fixation elements</p>

<p>the cannula; and</p>	<p>can also be accomplished through the device 10.” ’044 patent at col. 15, lines 3-4; ’487 patent at col. 15, lines 10-11; ’907 patent at col. 15, lines 3-4; ’648 published application at ¶ 0077.</p> <p>“In one specific embodiment, the fixation element can be a bone screw. . . . Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision.” ’044 patent at col. 15, lines 12-27; ’487 patent at col. 15, lines 20-36; ’907 patent at col. 15, lines 12-27; ’648 published application at ¶¶ 0077-0078.</p>
<p>installing the plurality of fixation elements at the surgical site to fix a first vertebra with respect to a second vertebra;</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the device 10. In this type of procedure, an incision can be made in the skin posterior to the location of the vertebra at which the fixation element is to be implanted. Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented. With the optics extending through the working channel, an insertion tool holding the vertebral fixation element can be projected through the cannula 20 and manipulated at the vertebra. In one specific embodiment, the fixation element can be a bone screw. The working channel 25 has a diameter that is large enough to accept most bone screws and their associated insertion tools. In many instances, the location of the bone screw within the vertebra is critical, so identification of the position of the cannula 20 over the bony site is necessary. As mentioned above, this position can be verified fluoroscopically or using stereotactic technology.</p> <p>In many prior procedures, cannulated bone screws are driven into the vertebra along K-wires. The present invention eliminates the need for the K-wire and for a cannulated screw. The working channel itself can effectively operate as a positioning guide, once the cannula 20 is properly oriented with respect</p>

	<p>to the vertebra. Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision. The surgeon can then readily verify that the screw is passing into the vertebra properly. This can be particularly important for bone screws being threaded into the pedicle of a vertebra. The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 3-34; ’487 patent at col. 15, lines 9-42; ’907 patent at col. 15, lines 12-27; ’648 published application at ¶¶ 0077-0078.</p>
<p>wherein said fixation elements include bone screws.</p>	<p>“In one specific embodiment, the fixation element can be a bone screw.” ’044 patent at col. 15, lines 12-13; ’487 patent at col. 15, lines 20-21; ’907 patent at col. 15, lines 3-34; ’648 published application at ¶ 0077.</p> <p>“The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” ’044 patent at col. 15, lines 31-34; ’487 patent at col. 15, lines 39-42; ’907 patent at col. 15, lines 31-34; ’648 published application at ¶ 0078.</p>